

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW
YORK, by LETITIA JAMES, Attorney
General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING
COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited
liability company;

PREVAGEN, INC., a corporation
d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE
MANUFACTURING, LLC, a limited
liability company; and

MARK UNDERWOOD, individually and as
an officer of QUINCY BIOSCIENCE
HOLDING COMPANY, INC., QUINCY
BIOSCIENCE, LLC, and PREVAGEN,
INC.

Defendants.

Case No. 1:17-cv-00124-LLS

**PLAINTIFFS' REPLY TO DEFENDANTS' OPPOSITION TO MOTION TO STRIKE
AFFIRMATIVE DEFENSES**

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I. INTRODUCTION

Plaintiffs, the Federal Trade Commission (“FTC”) and the People of the State of New York by Letitia James, Attorney General of the State of New York (“NYAG”) file this reply to the September 30, 2019 Memoranda of Law in Opposition to the Motion to Strike Affirmative Defenses submitted by Corporate Defendants Quincy Bioscience Holding Company, Inc. et al. (collectively “Quincy”) and Individual Defendant Mark Underwood. (Dkts. 87 and 88). For the reasons stated below and in Plaintiffs’ Motion to Strike (Dkt. 86-1), the challenged Affirmative Defenses should be stricken as legally invalid, factually insufficient, and prejudicial.

II. ARGUMENT

A. Defendants’ Affirmative Defenses Fail as Legally and Factually Insufficient Under Any Interpretation of Rule 12(f).

Defendants’ analysis and application of the legal standard for striking affirmative defenses pursuant to Fed. R. Civ. P. 12(f) is flawed for a number of reasons. First and foremost, Defendants engage in a lengthy discussion of the significance of the Second Circuit’s ruling earlier this year in *GEOMC*¹ in an effort to distract the Court from the fact that their defenses are entirely deficient, both factually and legally, under any standard of review. Their attempt to recast the *GEOMC* ruling as nothing more than a “slight refinement” of the standard for striking affirmative defenses and their objection to Plaintiffs’ reference to the “heightened” plausibility standard are distinctions without a difference in this case. (Dkt. 88 at 3-6). The challenged Affirmative Defenses are nothing more than formulaic recitations of legal buzzwords devoid of supporting facts and thus fail under any interpretation of *GEOMC* and under the more lenient standard that preceded it. *See, e.g., Schechter v. Comptroller of N.Y.*, 79 F.3d 265, 270 (2d Cir.

¹ *GEOMC Co. v. Calmare Therapeutics Inc.*, 918 F.3d 92 (2d Cir. 2019) (applying a plausibility standard to pleading of affirmative defenses).

1996); *Cartier Int'l AG v. Motion in Time, Inc.*, No. 12-cv-8216, 2013 WL 1386975, at *3 (S.D.N.Y. Apr. 5, 2013) (“[C]onclusory assertions absent any supporting factual allegations are insufficient as a matter of law.”). This Court should follow a precedent that was already clear well before the *GEOMC* ruling and strike all boilerplate defenses from this case.

Defendants also make much of the fact that the plausibility standard, as articulated in *GEOMC*, is a “context-specific task.” They suggest, therefore, that this Court should allow Defendants time to gather facts that may not be readily known to them without comprehensive discovery in order to adequately plead their defenses. (Dkt. 88 at 4). Their argument is disingenuous and should be rejected. Defendants fail to point to any specific area of inquiry for which the relevant information and documents are not already in their own control, in the public domain, or have been made available to them during briefing of their earlier Motions to Dismiss. For example, Defendants cannot credibly claim the need for further discovery on any defense that involves facts about Defendants’ knowledge and conduct (e.g. “good faith”). Similarly, while their defense that the FTC acted *ultra vires* arguably requires knowledge of the agency’s vote to issue a complaint, that vote is a matter of public record, and the specific documents recording the vote were submitted to the Court and served on Defendants as part of the briefing on the Motions to Dismiss.² The only defenses where further discovery could arguably produce facts not currently available to Defendants are their laches and waiver defenses. Those defenses, however, are not legally available in this action and have already been withdrawn by the Quincy Defendants.

² July 22, 2019 Declaration of FTC Secretary April Tabor and accompanying Jan. 3, 2017 Federal Trade Commission Circulation Record. (Dkt. 71-1).

Finally, Defendants misapply the third prong of the test for assessing the adequacy of affirmative defenses. They suggest that the Court should not even consider the prejudice to Plaintiffs of requiring invasive discovery on the challenged defenses. They then argue in the alternative that Plaintiffs have failed to set out sufficient details of prejudice. Neither is correct.

Defendants' reading of *GEOMC* is wrong. The court declined to consider prejudice in assessing affirmative defenses it found to be otherwise factually sufficient, legally valid, and timely filed. *GEOMC*, 918 F.3d at 98. Here, the challenged defenses are factually insufficient, legally invalid, and in some cases both. Because they will unnecessarily add to the duration and expense of trial, they are also prejudicial and should be stricken. *See, e.g., Coach Inc. v. Kmart Corps.*, 756 F. Supp. 2d 421, 426, 428-9 (S.D.N.Y. 2010). In *Coach*, the court turned to the question of prejudice after determining that various equitable defenses, including estoppel, laches, and waiver, were legally insufficient, stating simply that "inclusion of the above legally insufficient defenses would prejudice plaintiffs" by increasing the duration and expense of trial. *Id.* at 428.

Defendants also mischaracterize Plaintiffs' discussion of prejudice as lacking sufficient detail to warrant striking their defenses. (Dkt. 88 at 6). Defendant Underwood further asserts that the challenged Affirmative Defenses cannot be burdensome because they do not change the scope of discovery. (Dkt. 87 at 5). To the contrary, Plaintiffs have described how certain defenses would require them to waste time and resources relitigating defenses already fully briefed at the Motions to Dismiss stage and how other defenses could subject the agencies to extensive discovery about their internal workings and deliberations. Such invasive discovery has been found to be prejudicial. *See, e.g., FTC v. Consumer Health Benefits Ass'n*, No. 10 Civ. 3551 (ILG)(RLM), 2011 WL 13295634 at *8 (E.D.N.Y. Oct. 5, 2011) (striking multiple defenses

raised against FTC and noting that prejudice is clear where a defendant seeks to “discover the internal workings of the [FTC’s] investigations”). Plaintiffs have made an adequate showing of prejudice to justify striking the challenged Affirmative Defenses.

B. There is No Factual or Legal Basis for Revisiting the *Ultra Vires* Act Argument as an Affirmative Defense.

Defendants should not be allowed to relitigate the already rejected argument that the FTC acted *ultra vires* in voting to file its Complaint. That issue was fully briefed by the parties and resolved by this Court in its July 24, 2019 Order on Defendants’ Motion to Dismiss. *FTC v. Quincy Bioscience Holding Co.*, 389 F. Supp. 3d 211, 215-216 (S.D.N.Y. 2019). The ruling included a detailed discussion of all relevant facts relating to the Commissioners’ vote and a thorough analysis of the applicable law on what constitutes a valid quorum. *Id.* at 216. The Court held, simply and unequivocally, that the “FTC did not commence action *ultra vires*.” *Id.* at 211. Defendants’ attempt to characterize the Court’s action as something less than a rejection of the *ultra vires* argument (Dkt. 88 at 8) is belied by the clear language of the ruling.

This Court’s ruling is now the law of the case and, under the law of the case doctrine, “a decision on an issue made at one stage of a case becomes binding precedent to be followed in subsequent stages of the same litigation.” *In re PCH Assocs.*, 949 F.2d 585, 592 (2d Cir. 1991). The Second Circuit has “repeatedly stated [that it] will not depart from the law of the case absent cogent or compelling reasons.” *In re Nassau Cty. Strip Search Cases*, 985 F. Supp. 2d 339, 343 (E.D.N.Y. 2013) (quoting *Pescatore v. Pan Am. World Airways, Inc.*, 97 F.3d 1, 8 (2d Cir. 1996)). Reconsideration of an issue already decided is justified only by an intervening change in controlling law, new evidence, or the need to correct a clear error. *Virgin Atl. Airways, Ltd. v. Nat’l Mediation Bd.*, 956 F.2d 1245, 1255 (2d Cir. 1992).

Defendants provide no justification for revisiting the Court's ruling on the *ultra vires* argument. There has been no change in law; there is no allegation that the Court's ruling was clearly in error; and there is no new evidence to be reviewed. Defendants' assertion that they still lack knowledge of, and access to, relevant facts and thus require further discovery is demonstrably false. All pertinent information has been publicly available on the FTC's website since the Complaint was filed. That information includes how each Commissioner voted, the date of the vote, the number of vacancies on the Commission at the time, and the dates of each Commissioner's appointment. The FTC has even turned over the underlying documents pertaining to the vote, including the Commission's circulation record with the hand recorded date and time of each vote and the corresponding emails documenting those votes. (Dkt. 71-1).

The Second Circuit laid out the rationale for the law of the case doctrine, stating, "where litigants have once battled for the court's decision, they should neither be required, nor without good reason permitted, to battle for it again." *In re Nassau Cty. Strip Search Cases*, 958 F. Supp. 2d at 343–44 (quoting *Virgin Atl. Airways, Ltd.*, 956 F.2d at 1255). Plaintiffs should not have to waste time and resources battling this accusation a second time.

C. Defendant Underwood Should Follow Quincy's Lead and Withdraw the Laches and Waiver Defenses, Which are Unavailable as a Matter of Law

The Quincy Defendants have now withdrawn their Second Affirmative Defense (laches and waiver). (Dkt. 88 at 13). Defendant Underwood, however, continues to assert his corresponding defense (Dkt. 87 at 2) despite well-settled law that such equitable defenses are not available as a matter of law in actions brought by a government agency. Plaintiffs have provided several examples of cases in this Circuit where the courts have rejected these and other equitable defenses in cases brought by the FTC and the NYAG. (Dkt. 86-1 at 7-8); *see, e.g., FTC v. Crescent Pub. Grp., Inc.*, 129 F. Supp. 2d 311, 324 (S.D.N.Y. 2001).

Defendant Underwood contends that the bar on equitable defenses against the government is only a “general” rule, but makes no argument for why that general rule should not govern here. In fact, the courts in this Circuit have been clear that they will only consider making an exception to the general rule barring equitable defenses against the government if the “misconduct [is] egregious and the resulting prejudice to the defendant rise[s] to a constitutional level.” *In re Beacon Assoc. Litig.*, No. 09 Civ. 777 (AJP), 2011 WL 3586129, at *3 (S.D.N.Y. Aug. 11, 2011) (quoting *SEC v. Rosenfeld*, No. 97 Civ. 1467 (RPP), 1997 WL 400131, at *1-2 (S.D.N.Y. July 16, 1997)). There is no indication that Plaintiffs engaged in any misconduct, and Underwood does not plead any facts that would support the kind of egregious constitutional violation necessary to justify the rare exception to the general rule. In fact, Underwood’s Third Affirmative defense is devoid of any supporting facts.

Absent even a hint of wrongdoing by Plaintiffs, Underwood should not be permitted to engage in an invasive and burdensome fishing expedition into the agencies’ inner workings for a defense that is clearly unavailable in this action. If Underwood does not follow Quincy’s lead and voluntarily withdraw his laches and waiver defense, the Court should strike it as legally invalid, factually insufficient, and prejudicial because it would unnecessarily increase discovery costs and trial time.

D. Defendants’ Advertising and Sale of Prevagen in New York Provides the Basis for New York’s General Business Law Claims.

Defendants suggest that their Fifteenth Affirmative Defense rests on the fact that the Complaint includes transactions that took place outside of New York. (Dkt 88 at 9). The fact that some of the alleged deceptive acts and practices, including false advertising and sale of Prevagen, took place in states other than New York has absolutely no legal bearing on the sufficiency of the NYAG’s General Business Law Claims. The Complaint allegations as to

conduct in New York are clearly stated and must be accepted as true. (Dkt. 1 ¶¶ 9-14). The extent to which Quincy’s sales “took place outside of New York” is relevant only as to the calculation of appropriate remedies should the NYAG succeed in proving the alleged violation of New York law. There is no logic to Defendants’ assertion that the New York law claims “fail” merely because Defendants also conducted business in other states.

E. Defendants’ First Amendment Discussion Disregards the Presumptive Truth of the Complaint and Relies on Legal Arguments Relevant Only to Defenses Not Challenged By Plaintiffs.

Defendants raise multiple First Amendment defenses in their Answers, but Plaintiffs have moved to strike only one – that “the advertising claims challenged by Plaintiffs in the Complaint are protected commercial speech.” (Quincy Sixth Affirmative Defense and Underwood Seventh Affirmative Defenses). In considering the sufficiency of an affirmative defense, the courts accept all well-pleaded factual allegations in the complaint as true and draw all reasonable inferences in the plaintiff’s favor. *Coach Inc.*, 756 F. Supp. 2d at 428. The Complaint alleges that Defendants’ advertising for Prevagen is false or unsubstantiated, and therefore, deceptive. (Dkt. 1 at 26-29). Those allegations are presumptively true for purposes of this Motion, and there is no dispute that the challenged advertising is commercial in nature. Given the well-settled law that deceptive commercial speech is entitled to no First Amendment protection, there is no need for further analysis. *See, e.g., Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 638 (1985) (holding that it is “well settled” that “[t]he States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading.”); *Bristol-Myers Co. v. FTC*, 738 F.2d 554, 562 (2d Cir. 1984) (deceptive advertising enjoys no constitutional protection); *Jay Norris, Inc. v. FTC*, 598 F.2d 1244, 1252 (2d Cir. 1979). The defense that the challenged advertising claims are protected commercial speech fails as a matter of law.

Defendants' Opposition Memorandum makes clear that this is not even a true affirmative defense, but rather a factual disagreement as to the merits of the case – *i.e.*, whether or not the challenged advertising claims are adequately substantiated. Defendants discuss the quality and design of the study they conducted and contend that the study supported their advertising claims. That is the fundamental question to be resolved at trial. If Defendants succeed in establishing that the ads were not deceptive, then they did not violate FTC and New York law and the Court need not reach the First Amendment issue. If the ads are found to be deceptive, they enjoy no constitutional protection. In *FTC v. North America Mktg. and Assoc., LLC*, the court struck a similar First Amendment defense, reasoning that it was a factual disagreement on the merits of the FTC's case and thus not even the proper subject of an affirmative defense. No. CV-12-0914-PHX-DGC, 2012 WL 5034967, at *2 (D. Ariz. Oct. 18, 2012).

Defendants' Opposition Memorandum also appears to confound their multiple First Amendment Defenses, relying on case law that is relevant only to defenses that Plaintiffs have not moved to strike.³ The Memorandum shifts into a discussion of what restrictions on advertising claims might be imposed in an order, should Plaintiffs prevail on the merits, citing to *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980) and *POM Wonderful, LLC v. FTC*, 777 F.3d 478 (D.C. Cir. 2015). (Dkt. 88 at 12-13). The appropriate scope of such restrictions under the test set out in the *Central Hudson* and applied in *Pom Wonderful*, is relevant only to the relief sought as to future advertising, not to the question of whether the presumptively deceptive commercial speech challenged in the Complaint is protected by the First Amendment. Although Plaintiffs consider Defendants' Affirmative

³ Plaintiffs did not move to strike Quincy's Seventh and Eighth Affirmative Defenses and Underwood's Eighth Affirmative Defense, which all challenge the relief sought in this case as violative of the First Amendment. (Dkt. 73 at 9); (Dkt. 74 at 9).

Defenses related to future remedies in this case to be both premature and speculative, they are not the subject of this Motion, and the cases cited by Defendants do not support the single First Amendment defense that Plaintiffs have moved to strike.

F. FDA’s Overlapping Jurisdiction In No Way Limits Plaintiffs’ Authority to Bring this Action.

Defendants cite no cases, statutory authority, or regulations to support their position that Plaintiffs’ authority to bring this case is restricted by the fact that another agency, the Food and Drug Administration, also has jurisdiction over dietary supplements. They cite none because there are none. FDA law and regulations are a completely different regulatory scheme and simply do not govern this case. Plaintiffs’ Memorandum in support of this Motion cites multiple cases where the courts have repeatedly and unequivocally rejected the idea that FDA’s overlapping regulatory authority in any way restricts the FTC. (Dkt. 86-1 at 9-10); *see, e.g., Thompson Medical Co. v. FTC*, 791 F.2d 189, 192 (D.C. Cir. 1986) (“Nowhere in the case law or in the FTC’s grant of authority is there even a hint that the FTC’s jurisdiction is so constricted.”). Defendants now try to argue that some of those cases are not pertinent here merely because they involved over-the-counter drugs, and Prevagen is a dietary supplement. (Dkt. 88 at 17). The distinction is immaterial. The “Memorandum of Understanding” between the FTC and FDA lays out the agencies’ voluntary coordination of enforcement activity and applies the exact same approach whether the product is a food, dietary supplement, or OTC drug. *Working Agreement between FTC and FDA*, 36 Fed. Reg. 19539 (1971) (“MOU”). The case law cited by Plaintiffs is directly on point.

Defendants have engaged in a false syllogism in interpreting that MOU. As Plaintiffs explained and Defendants acknowledge, the MOU provides that the FTC generally takes the enforcement lead where the false or misleading claims appear predominantly in advertising, and

the FDA generally takes the lead where such claims are limited to labeling. *Id.* When the FTC brings a case against the deceptive marketing of a food, dietary supplement, or OTC drug, however, that case covers all deceptive claims *wherever they appear, in any form of marketing, including advertising and labeling*. The MOU merely provides guidance on which agency will bring the case. The purpose of this approach is to avoid duplication of effort, not to restrict either agency's authority over advertising and labeling. It does not mean that when the FTC takes the lead, rather than FDA, defendants get a free pass on deceptive claims on their product package. Most marketing campaigns repeat claims in both advertising and labeling. It would be a perverse result if the FDA had to bring its own enforcement action challenging the very same misconduct, merely because some of the deceptive marketing appeared on the product package.

The false premise that FDA's authority over dietary supplements is a bar to any part of this action is belied by a long and active enforcement history of both the FTC and the NYAG to stop false and misleading supplement marketing. That enforcement routinely involves challenging claims that appear in advertising *and* labeling and results in orders that cover both. As one example, in 2008 the FTC prevailed in a summary judgment motion challenging deceptive marketing of dietary supplements for weight loss and erectile dysfunction by two companies and three individual shareholders/officers. *FTC v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167 (N.D. Ga. 2008), *aff'd*, 356 Fed. Appx. 358 (11th Cir. 2009). The resulting Final Judgment and Permanent Injunction, among other things, prohibited false and misleading claims in all forms of advertising, labeling, and promotion.⁴ As another example, the NYAG reached

⁴ See Final Judgment and Permanent Injunction at 10-16, *FTC v. Nat'l Urological Grp., Inc.*, No. 1:04-CV-3294-CAP (N.D. Ga. Dec. 6, 2008) (Dkt. 230). A true and correct copy of the Final Judgment and Permanent Injunction, with accompanying Declaration of Michelle K. Rusk, is submitted as Exhibit A.

agreements with multiple herbal supplement manufacturers requiring them to conduct testing, labeling, and manufacturing reforms in order to ensure their products' purity and educate consumers about the supplements' chemical content. *See A.G. Schneiderman Announces Major Nationwide Agreement with NBTY, Herbal Supplement Maker for Walgreens and Walmart* (Sept. 28, 2016), available at <https://ag.ny.gov/press-release/2016/ag-schneiderman-announces-major-nationwide-agreement-nbty-herbal-supplement-maker>. The "FDA primary jurisdiction" defense should be stricken. It would set a harmful precedent not just for the agencies in this case but for the many other instances where multiple agencies at the federal and state level share overlapping authority. Absent clear evidence to the contrary, such overlap should never be construed as restricting one agency's authority over another. As the D.C. Circuit noted in *FTC v. Ken Roberts, Co.*, "[b]ecause we live in an age of overlapping and concurring regulatory jurisdiction, a court must proceed with the utmost caution before concluding that one agency may not regulate merely because another may." 276 F.3d 583, 593 (D.C. Cir. 2001) (quoting *Thompson Med. Co.* 791 F.2d at 192).

III. CONCLUSION

For the reasons stated above, Plaintiffs request that the Court strike the following Affirmative Defenses: Defendants Quincy Bioscience Holding Co., et al.'s First, Second, Fifth, Sixth, Tenth, Thirteenth, Fifteenth, and Seventeenth Defenses; Defendant Underwood's First, Third, Sixth, Seventh, Tenth, Thirteenth, and Fifteenth Defenses, and the Preamble to Underwood's Affirmative Defenses reserving the right to raise other defenses.

Dated: October 7, 2019

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CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of October, 2019, I have caused service of the foregoing Plaintiff's Reply to Defendants' Opposition to Motion to Strike Affirmative Defenses to be made by electronic filing with the Clerk of the Court using the CM/ECF system, which will send a Notice of Electronic Filing to all counsel of record.

Dated: October 7, 2019
Washington, D.C.

/s/ Michelle Rusk
Michelle Rusk